

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 14-932V

February 20, 2015

Not to be Published

J.O., a Minor, by his Parents, *
DEBI OLIVEIRA and TONY OLIVEIRA, *

Petitioners, *

v. * Hepatitis A and Menactra vaccines;

SECRETARY OF HEALTH * causation or significant aggravation
AND HUMAN SERVICES, * of Crohn's disease; no expert witness;

Respondent. *

William E. Cochran, Jr., Memphis, TN, for petitioners.

Lisa A. Watts, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

On October 2, 2014, petitioners herein sued on behalf of their son J.O. by filing a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10-34 (2006), alleging that hepatitis A and meningococcal ("Menactra") vaccines caused J.O.'s Crohn's disease, or, in the alternative, significantly aggravated his preexisting Crohn's disease.

¹ Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioners have 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

Under the Vaccine Act, “significant aggravation” is defined as “any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.” 42 U.S.C. § 300aa-33(4).

Crohn’s disease is defined as “one of the principal forms of inflammatory bowel disease, a chronic granulomatous disease of the gastrointestinal tract of unknown etiology; it can involve any part of the tract, but most often is found in the terminal ileum. Characteristics include scarring and thickening of the bowel wall that frequently leads to intestinal obstruction, abscesses, and fistula formation. There is a high rate of recurrence after treatment.” Dorland’s Illustrated Medical Dictionary 531 (32d ed. 2012) (“Dorland’s”).

“[C]hronic diarrhea is the most common presenting complaint[,] and abdominal pain and weight loss are present in over 60% of [Crohn’s disease] patients at diagnosis.” Textbook of Gastroenterology 1402 (T. Yamada ed., 5th ed. 2009). In addition, “[I]ntercurrent infections . . . may impact on symptoms or inflammatory features.” Id. at 1404.

On October 31, 2014, the undersigned issued a lengthy Order, describing the contents of the medical records as well as the issues in the case. The undersigned discussed the October 31, 2014 Order with counsel on November 5, 2014, during the first telephonic status conference.

On December 11, 2014, respondent filed her Rule 4(c) Report, stating that compensation is not appropriate in this case because J.O.’s Crohn’s disease began before his hepatitis A and Menactra vaccinations, and petitioners had not filed a medical expert report supporting the allegation that his vaccinations significantly aggravated his pre-existing Crohn’s disease.

On December 17, 2014, the undersigned held another telephonic status conference with counsel. Petitioners’ counsel stated he was looking for a medical expert, and he had shared both the undersigned’s October 31, 2014 Order and respondent’s Rule 4(c) Report with petitioners.

On February 19, 2015, the undersigned held another telephonic status conference with counsel. Petitioners’ counsel orally moved to dismiss this case.

The undersigned **GRANTS** petitioners’ motion and **DISMISSES** this case for failure to prove that hepatitis A and Menactra vaccinations caused or, in the alternative, significantly aggravated J.O.’s Crohn’s disease.

FACTS

J.O. was born on November 9, 1999.

On February 22, 2013, J.O. visited his personal care physician (“PCP”), Dr. Anthony Marinello, at Capital Care Family Practice. Med. recs. Ex. 4, at 22–23. Dr. Marinello noted his concern about whether J.O. had food allergies to milk and gluten, based on J.O.’s previous

complaints that he had adverse experiences when he drank milk and/or ate anything with gluten, such as wheat. Id. at 22. J.O.'s complaint to Dr. Marinello preceded his receipt of hepatitis A vaccine and Menactra on February 22, 2013. Id.

This visit to Dr. Marinello occurred two days before J.O. visited his grandfather on February 24, 2013, for his grandfather's birthday. At the grandfather's birthday celebration, J.O.'s mother had an upset stomach, vomiting, and diarrhea. Ex. 6, at 2. Within a few days, J.O. had the gastroenteritis his mother had. Id.

Eleven days after his grandfather's birthday, on March 7, 2013, and approximately one week after J.O. caught his mother's gastroenteritis, J.O. saw an allergist, Dr. Ari Kounavis, and gave a history that he had had diarrhea associated with meals for the prior three months. Med. recs. Ex. 2, at 4. The diarrhea occurred one hour after breakfast, after school, and after dinner. Id. J.O. had dairy with each meal. Id. The diarrhea looked like watery loose stools without blood in them. Id. One week earlier (which would be around February 28), he had dark red blood in his stool. Id. One month previously, he also had been vomiting for two days associated with gastroenteritis. Id. J.O. had been drinking more cow's milk and eating pasta and wheat over the past six months in order to increase his weight for sports, but he had been losing weight instead of gaining it. Id. Skin testing for allergy to cow's milk and wheat was negative. Id. at 6. (From this record, we see that J.O. was experiencing weight loss over the prior six months even though he was eating more, that he had been experiencing diarrhea associated with meals for the prior three months, and that he had been sensitive to milk and wheat although he tested negatively for an allergy to both substances. His weight loss in the context of increased caloric intake, abdominal upset, and diarrhea occurred before his hepatitis A and meningitis vaccinations.)

On March 28, 2013, three weeks after J.O. saw the allergist Dr. Kounavis, J.O. saw Dr. Nikki Allmendinger, a pediatric gastroenterologist, at Albany Medical Center. Med. recs. Ex. 1A, at 18. J.O. gave a similar history to Dr. Allmendinger that he had given to Dr. Kounavis, but with additional information. Id. (Dr. Kounavis and Dr. Allmendinger work at different medical facilities, and there is nothing in the records to suggest that Dr. Allmendinger had access to Dr. Kounavis's records and copied J.O.'s history from them. Thus, two independent histories from J.O. establish his Crohn's symptomatology preceded his vaccinations, in addition to his history to Dr. Marinello of digestive problems preceding vaccination.)

J.O. told Dr. Allmendinger that for at least the last three months, he had been having daily diarrhea of a small amount, and he only had a formed stool once a week or so. Id. There was no blood in the stool. Id. At the beginning of all this, J.O. and other family members were sick with vomiting and diarrhea, but J.O.'s diarrhea continued. Id. When his parents removed dairy from his diet, he had some improvement, although he still had issues. Id. He returned to milk again four days before the appointment and seemed to be a little worse. Id. He complained of abdominal pain once a week that was relieved with stooling. Id. Spicy foods made him feel worse. Id. Dr. Allmendinger commented that J.O. did not seem to have a very well balanced

diet. Id. J.O. ate a lot of carbohydrates and meats, but not a lot of fruits and vegetables. Id. J.O. had been attempting to gain weight by ingesting more calories, but he had not been gaining weight. Id. J.O. was in the 37th percentile for weight, but in the 56th percentile for height. Id. at 19. He had iron deficiency anemia, elevated sedimentation rate, diarrhea, and poor weight gain. Id.

On April 8, 2013, Dr. Allmendinger performed a colonoscopy on J.O. and diagnosed him with disorder of the intestine, ulceration of the intestine, diarrhea, and blood in his stool. Med. recs. Ex. 1B, at 1. On April 16, 2013, Dr. Allmendinger diagnosed J.O. with Crohn's disease. Med. recs. Ex. 1A, at 16.

On April 19, 2013, Dr. Marinello referred J.O. to an ear-nose-throat ("ENT") specialist because he had an inflamed epiglottis. Med. recs. Ex. 4, at 2.

On April 29, 2013, J.O. saw Dr. Michael De Vito, an ENT, who diagnosed J.O. with allergic rhinitis. Id. at 21. J.O. suffered from allergies throughout the year. Id.

On November 11, 2013, J.O.'s mother requested Dr. Allmendinger write a letter, as she felt there might be a connection between J.O.'s Crohn's disease and the MMRV vaccine that J.O. received on February 22, 2013, because his symptoms developed about a week after it. Med. recs. Ex. 1A, at 11.

J.O. did not receive MMR and varicella vaccines on February 22, 2013. He received hepatitis A vaccine and Menactra on that date. Med. recs. Ex. 4, at 4. MMR and varicella vaccines are attenuated live viral vaccines. MMRV vaccine, Wikipedia, http://www.wikipedia.org/wiki/MMRV_vaccine (last visited Feb. 20, 2015). Hepatitis A vaccine is a killed virus vaccine. Hepatitis A Vaccine and Prevention, eMedicineHealth, http://www.emedicinehealth.com/hepatitis_a/page11_em.htm (last updated Dec. 15, 2014). Menactra is a meningococcal conjugated vaccine. Dorland's at 1131. Its purpose is to prevent the bacterial disease meningitis, and there is no virus in it. Meningococcal Vaccine, WebMD, <http://www.webmd.com/children/vaccines/meningococcal-vaccine> (last visited Feb. 20, 2015).

DISCUSSION

To satisfy their burden of proving causation in fact, petitioners must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of Health and Human Services, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by “proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]” the logical sequence being supported by a “reputable medical or scientific explanation[,]” *i.e.*, “evidence in the form of scientific studies or expert medical testimony[.]”

418 F.3d at 1278.

Without more, “evidence showing an absence of other causes does not meet petitioners’ affirmative duty to show actual or legal causation.” *Grant*, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. *Id.* at 1148.

Petitioners must show not only that but for hepatitis A and Menactra vaccinations, J.O. would not have Crohn’s disease or significant aggravation of his Crohn’s disease, but also that the vaccines were a substantial factor in causing or significantly aggravating his Crohn’s disease. *Shyface v. Sec’y of HHS* 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act does not permit the undersigned to rule for petitioners based on their claims alone, “unsubstantiated by medical records or by medical opinion.” 42 U.S.C. § 300aa-13(a)(1). In this case, J.O.’s medical records do not substantiate petitioners’ claims. Moreover, petitioners have not filed an expert medical opinion substantiating their claims.

The undersigned **GRANTS** petitioners’ motion to dismiss and **DISMISSES** this case for petitioners’ failure to prove by a preponderance of the evidence the matters required in the petition. 42 U.S.C. § 300aa-13(a)(1).

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.²

IT IS SO ORDERED.

February 20, 2015
DATE

s/Laura D. Millman
Laura D. Millman
Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.